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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,376

05/02/2006

Claus Harder

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EXAMINER

GANESAN, SUBA

ART UNIT

PAPER NUMBER

3774

NOTIFICATION DATE

DELIVERY MODE

07/09/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com
akron-docket@hotmail.com

Office Action Summary	Application No. 10/562,376	Applicant(s) HARDER ET AL.	
	Examiner SUBA GANESAN	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/9/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/9/2009 has been entered.

Status of the Claims

1. Claims 1-2, and 4-5 are currently pending. Claim 1 has been amended on 4/9/2009.

Response to Arguments

2. Applicant's arguments with respect to claims 1-2 have been considered but are moot in view of the new grounds for rejection.

3. Applicant's arguments with respect to claims 4-5 have been considered but are not persuasive. In response to applicant's argument that the combination of Santos and Johnson would change the principle operation of Johnson, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

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4. In the instant case, Johnson teaches a release profile in which two therapeutic agents are delivered together such that the first drug has a higher concentration at the ends of the stent and a second drug has a higher concentration in the middle of the stent. Santos discloses variable release profiles for therapeutic agents, including various means to create such a variable release profile. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the stent of Santos with the release profile of Johnson, for the purpose of treating restenosis with multiple drugs.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santos et al. (U.S. Pat. No.: 7,169,178) in view of Buscemi (U.S. Pat. No.: 5,464,450).

3. Santos discloses a stent comprising a tubular basic body with a coating system comprising a polymer carrier and a pharmaceutically active substance (see abstract) wherein a concentration of the pharmaceutically active substance in the coating varies in the longitudinal direction of the stent (see fig. 5), such that the pharmaceutically active substance exhibits predetermined locally different elution characteristics in the longitudinal direction of the stent (see fig. 2b). The polymer carrier is biodegradable (see coating materials (col. 9 lines 1-30) for example, poly(L-lactic acid) or collagen).

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4. With respect to claim 3, Santos discloses biodegradable polymer carriers; however, Santos is silent as to whether the degradation behavior of the carrier serves to differentiate local elution characteristics. If not inherent in the disclosure of Santos, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the degradation characteristics of the polymer to differentiate local elution characteristics, since the rate of polymeric degradation would affect the amount of drug released from that polymer.

5. Buscemi specifically teaches the use of degradable stent materials, where the drugs are released into the body as the material degrades, at rates controlled by the rates of degradation of the biodegradable material (See abstract). If not inherent in the disclosure of Santos, it would have been obvious to one of ordinary skill in the art in view of the teaching of Buscemi to utilize degradation rates to control the rate of drug elution.

6. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santos et al. (U.S. Pat. No.: 7,169,178) in view of Johnson (U.S. Pat. No.: 5,972,027).

7. Santos is explained supra. However, Santos lacks a concentration of drug greater adjacent the face surfaces than the middle, or a second drug with a greater concentration in the middle than the face surfaces. Johnson teaches the use a release profile of multiple drugs with different concentrations based on the porosity of the stent (see fig. 5 and col. 4 lines 33-50) for the purpose of treating restenosis with multiple drugs. It would have been obvious to one of ordinary skill in the art at the time the

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invention was made to have provided the coated stent with variable drug concentration in the coating as disclosed by Santos with the release profile as taught by Johnson such that a first drug has a higher concentration at the ends of the stent and a second drug has a higher concentration in the middle of the stent, for the purpose of treating restenosis with multiple therapeutic agents.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./

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/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774